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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,208	05/01/2001	Andrew Saxon	UC067.002A	6410

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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,208	Applicant(s) SAXON ET AL.	
	Examiner Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 77, 79-81 and 83-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 93 is/are allowed.
- 6) ☒ Claim(s) 77, 79-81, 83-92, and 94-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/14/06; 12/13/05; 1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/06 has been entered.
2. Claims 77, 79-81 and 83-96 are pending and are being acted upon in this Office Action.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claims 94 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "fusion protein molecule" in dependent claims 94 and 95 is ambiguous and indefinite because the fusion protein in base claim 93 is closed ended. It cannot have extra second identical fusion molecule covalently linked to the fusion protein of SEQ ID NO: 7 through one or more disulfide bonds. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that claim 94 be amended to recite "A homodimer wherein said homodimer comprises the fusion molecule of claim 93 covalently linked to a second identical fusion molecule." It is suggested that claim 95 be amended to recite "The homodimer wherein the linkage is through one or more disulfide bonds."
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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6. Claims 77, 79-81, 83-92 and 96 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhu et al (Abstract 273, Clinical Immunology 99(1): 193, April 19, 2001; PTO 1449).

Zhu et al teach an isolated fusion molecule such as GE2 comprising a human IgG1 heavy chain constant region sequence such as γ Hinge-CH γ 2-CH γ 3 capable of binding to human IgG inhibitory receptor such as Fc γ RIIb directly functionally connected to a human IgE heavy chain constant region sequence such as CH ϵ 2-CH ϵ 3-CH ϵ 4 capable of binding to the human IgE receptor such as Fc ϵ RI (see abstract, page 193, second col., in particular). The reference IgG heavy chain constant region in the fusion protein is connected to the IgE heavy chain constant region via a polypeptide of 15 amino acid residues, which is within the claimed 5 to 25, 10 to 25 or 15 to 25 amino acid residues (see abstract, page 193, second col., in particular). The γ Hinge-CH γ 2-CH γ 3 of the reference fusion protein inherently binds to the human low affinity Fc γ RIIb. The CH ϵ 2-CH ϵ 3-CH ϵ 4 of the reference fusion protein binds to the native human high affinity Fc ϵ RI (see abstract, page 193, col. 2, in particular) and inherently also binds to the low affinity receptor Fc ϵ RII to inhibit IgE mediated release of histamine (see abstract, page 193, col. 2, in particular). The reference γ Hinge-CH γ 2-CH γ 3 of human IgG1 in the reference fusion protein inherently has the same amino acid sequence as the claimed γ Hinge-CH γ 2-CH γ 3 of human IgG1 of SEQ ID NO: 3. The reference CH ϵ 2-CH ϵ 3-CH ϵ 4 portion of the human IgE heavy chain constant region inherently has the same amino acid sequence as the claimed CH ϵ 2-CH ϵ 3-CH ϵ 4 portion of the human IgE of SEQ ID NO: 6.

The reference GE2 fusion molecule inherently capable of forming homodimer through one or more disulfide bonds because of the cysteine residues located within the hinge portion of the constant region of human IgG1. Zhu et al teach the reference gamma-epsilon fusion protein (GE) has the potential for use in IgE mediated allergic diseases by binding to both Fc ϵ RI and Fc γ R and thereby inhibits mast cell/basophil function (see abstract on page 193, col. 2, in particular). Thus, the reference teachings anticipate the claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (Abstract 273, Clinical Immunology 99(1): 193, April 19, 2001; PTO 1449) in view of US Pat No 5,116,964 (May 1992; PTO 892).

The teachings of Zhu et al have been discussed supra.

The invention in claim 85 differs from the teachings of the references only in that the fusion molecule wherein the IgG heavy chain constant region is from the heavy chain constant region of IgG₂, IgG₃ or IgG₄ instead of IgG₁.

The '964 patent teaches various hybrid immunoglobulin such as IgG heavy chain constant region from IgG₁, IgG₂, IgG₃ and IgG₄ fused to high affinity IgE receptor (see col. 1, lines 35-39, col. 10, lines 10-15, claims 5-7 of the '964 patent, in particular). The '964 patent teaches constant region of IgG₁, IgG₂, IgG₃ or IgG₄ when fused to a binding partner prolongs the in vivo plasma half life of the fusion protein and maintains effector function such as complement binding and binding to the human gamma receptor (see col. 4, lines 27-50, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the human IgG₁ heavy chain constant region in the Fcγ-Fcε as taught by Zhu et al for the human IgG₂, IgG₃ or IgG₄ constant region as taught by the '964 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.


One having ordinary skill in the art would have been motivated to do this because the constant region of IgG₂, IgG₃ or IgG₄ when fused to a binding partner prolongs the in vivo plasma half life of the fusion protein and maintains effector function such as complement binding

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and binding to the human gamma receptor as taught by the '964 patent (see col. 4, lines 27-50, in particular).

10. Claim 93 is allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
12. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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